

Section I (Amendments to the Claims)

Please amend claim 8, cancel claim 15 and add new claims 16-26 as set out below in the complete listing of claims of the application.

1. (Previously Presented) A process according to claim 8, comprising:
 - a) forming VA-2914 isopropanol hemisolvate crystals by means of crystallizing VA-2914 in isopropanol;
 - b) separating the VA-2914 isopropanol hemisolvate crystals; and
 - c) converting VA-2914 isopropanol hemisolvate into VA-2914.
2. (Original) A process according to claim 1, wherein formation of VA-2914 isopropanol hemisolvate crystals comprises dissolving VA-2914 in isopropanol under heat, and subsequent cooling of the resulting solution, optionally under stirring.
3. (Original) A process according to claim 2, wherein the VA-2914 and isopropanol mixture is heated at a temperature comprised between 75°C and the solvent reflux temperature, until complete dissolution of VA-2914, and subsequently, the resulting solution of VA-2914 in isopropanol is allowed to cool at a temperature comprised between 0°C and 30°C.
4. (Original) A process according to claim 1, wherein the VA-2914 isopropanol hemisolvate crystals are separated by filtration.
5. (Original) A process according to claim 1, wherein conversion of VA-2914 isopropanol hemisolvate into VA-2914 is carried out by recrystallization in a solvent.
6. (Original) A process according to claim 5, wherein conversion of VA-2914 isopropanol hemisolvate into VA-2914 is carried out by recrystallization in a solvent chosen between ethanol/water and ethyl ether.

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7. (Previously Presented) A process according to claim 8, wherein said VA-2914 compound is obtained by acid hydrolysis of compound 3,3-(1,2-ethanedioxy)-5 α -hydroxy-11 β -(4-N,N-dimethylaminophenyl)-17 α -acetoxy-19-norpregna-9-ene-20-one [carbinol acetate].

8. (Currently Amended) A process for purifying 17 α -acetoxy-11 β -(4-N,N-dimethylaminophenyl)-19-norpregna-4,9-diene-3,20-dione (VA-2914) comprising:
~~recrystallizing raw VA-2914 in isopropanol and forming VA-2914 isopropanol hemisolvate by dissolving VA-2914 in isopropanol under heat,~~
~~cooling the resulting solution to obtain crystalline VA-2914 isopropanol hemisolvate, and~~
~~isolating the crystalline VA-2914 isopropanol hemisolvate from the mother liquor.~~

9. (Original) 17 α -acetoxy-11 β -(4-N,N-dimethylaminophenyl)-19-norpregna-4,9-diene-3,20-dione (VA-2914) isopropanol hemisolvate, characterised in that:

it shows a potassium bromide pellet IR spectrum substantially similar to that shown in Figure 1, having significant bands at 1684, 1660, 1609, 1595, 1560, 1543, 1513, 1476, 1458, 1438, 1394, 1364, 1353, 1317, 1303, 1260, 1235, 1214, 1201, 1168, 1137, 1089, 1076, 1063, 1042, 1015, 965, 949, 922, 863, 830, 822, 795, 771, 734, 699, 668, 642, 617, 608, 592, 574, 537, 495 and 467 cm⁻¹;

the exotherm by differential scanning calorimetry (DSC) shows a peak at about 156°C; and

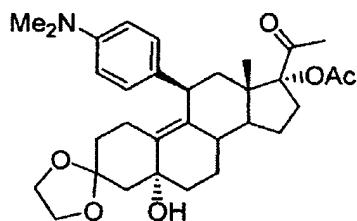
it shows an X-ray diffractogram (powder) substantially similar to that shown in Figure 3, with characteristic peaks at 8.860, 9.085 and 16.375 degrees 2 theta (2 θ).

10. (Original) A process for obtaining 17 α -acetoxy-11 β -(4-N,N-dimethylaminophenyl)-19-norpregna-4,9-diene-3,20-dione (VA-2914) isopropanol hemisolvate according to

claim 9, comprising dissolving VA-2914 in isopropanol under heat and allowing the resulting solution to cool to a temperature comprised between 0°C and 30°C.

11. (Cancelled)

12. (Previously Presented) The compound 3,3-(1,2-ethanediyo)-5 α -hydroxy-11 β -(4-N,N-dimethylamino-phenyl)-17 α -acetoxy-19-norpregna-9-ene-20-one [carbinol acetate], of the formula:



13. (Previously Presented) A method of producing 17 α -acetoxy-11 β -(4-N,N-dimethylaminophenyl)-19-norpregna-4,9-diene-3,20-dione (VA-2914), comprising providing VA-2914 isopropanol hemisolvate; and desolvating the VA-2914 isopropanol hemisolvate, to convert VA-2914 isopropanol hemisolvate to VA-2914.

14. (Previously Presented) A method according to claim 13, wherein said desolvating comprises recrystallizing VA-2914 isopropanol hemisolvate in a solvent selected from the group consisting of ethanol/water solvent and ethyl ether solvent.

15. (Cancelled)

16. (New) The process of Claim 1, wherein the VA-2914 is in the form of a white crystalline solid.

17. (New) The process of Claim 1, wherein the VA-2914 has a melting point of around 189°C.

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18. (New) VA-2914 isopropanol hemisolvate prepared by a process comprising:
 - a) dissolving VA-2914 in isopropanol at a temperature between 75°C and the solvent reflux temperature,
 - b) allowing the resulting solution to cool down to a temperature between 0°C and 30°C, and
 - c) isolating the resulting VA-2914 isopropanol hemisolvate crystalline form.
19. (New) The method of Claim 18, further comprising the step of converting the VA-2914 isopropanol hemisolvate to VA-2914 via recrystallization of the VA-2914 isopropanol hemisolvate in a solvent other than isopropanol.
20. (New) The method of Claim 19, wherein the recrystallization solvent is ethyl ether or a mixture of ethanol and water.
21. (New) The method of Claim 19, wherein the VA-2914 is obtained in the form of white crystals.
22. (New) The method of Claim 19, wherein the VA-2914 has a melting point of around 189°C.
23. (New) Isolated VA-2914 isopropanol hemisolvate in crystalline form.
24. (New) Isolated VA-2914, in the form of white crystals.
25. (New) Isolated VA-2914, in the form of crystals with a melting point of around 189°C.
26. (New) Isolated VA-2914, in the form of white crystals with a melting point of around 189°C.